IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BIOGEN INTERNATIONAL GMBH and BIOGEN MA INC.,	)	
Plaintiffs,	)	**C.A. No. 17-823-MN (Consolidated)**
v.	)	
AMNEAL PHARMACEUTICALS LLC, et. al,	)	
Defendants.	)	

BIOGEN'S SUR-REPLY BRIEF ON VALIDITY OF THE '514 PATENT

Of Counsel:

James B. Monroe
Eric J. Fues
Laura P. Masurovsky
Paul W. Browning
Li Feng
Andrew E. Renison
John E. Nappi
Jeanette M. Roorda
Aaron G. Clay
FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER, LLP
901 New York Ave., N.W.
Washington, D.C. 20001
(202) 408-4000

Megan L. Meyers
FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER, LLP
271 17th Street NW, Suite 1400
Atlanta, GA 30363
(404) 653-6565

ASHBY & GEDDES
Steven J. Balick (#2114)
Andrew C. Mayo (#5207)
500 Delaware Avenue, 8th Floor
P.O. Box 1150
Wilmington, Delaware 19899
(302) 654-1888
sbalick@ashbygeddes.com
amayo@ashbygeddes.com

Attorneys for Plaintiffs

Dated: March 16, 2020

I. INTRODUCTION

While Biogen did not oppose Defendants' motion (D.I. 372) seeking leave to file their Reply to Biogen's Responsive Post-Trial Brief (D.I. 372-1 Ex. A ("DEF Reply")), Biogen disputes Defendants' arguments and files this response.

Defendants bore the burden of proving their invalidity defenses, including their written description defense, by clear and convincing evidence. Because each patent claim is separately patentable, that clear and convincing evidence burden applies to each of the asserted patent claims. Defendants broadly asserted their invalidity defenses as to the asserted claims taken as a whole and failed to separately demonstrate the invalidity of any of the claims. Simply put, Defendants failed to provide proof of alleged invalidity on a claim by claim basis and cannot now fill that hole. (*See* Tr. 907:20-908:4.)

Having made this strategic decision, Defendants have no cause to protest that Biogen has pointed out that their generalized arguments do not account for the variations in the asserted claims, including independent Claim 11. Defendants are mistaken that Biogen somehow conceded that the asserted claims are the same and thus Defendants arguments of estoppel and waiver are without merit.

II. ARGUMENT

Defendants point to two instances in the record that they contend show that Biogen allegedly admitted a "consistent" position reflecting a "mutual understanding" that the asserted claims are all the same and all include a "therapeutically effective" limitation. (DEF Reply at 1-2.) Neither instance supports Defendants' erroneous position.

First, Defendants' citation to Biogen's counsel's response to the Court's questioning during closing argument does not support their position. (DEF Reply at 2 citing Tr. 910:11-911:22.) Biogen did not state that all the asserted claims, including independent Claim 11, should be treated

the same with respect to Defendants' defenses. Rather, Biogen's counsel was responding to the Court's questioning about dependent claims: "is there anything in the dependent claims that you would assert renders them separately patentable?" (Tr. 910:16-18.) Biogen's counsel responded that the dependent claims would rise and fall together with the corresponding independent claim with respect to written description, because the dependent claim elements were not disputed by Defendants in their written description argument. (Tr. 910:15-911:17.) Thus, counsel for Biogen did not, as defendants suggest, indicate that all independent claims rise and fall together and therefore can be treated the same with respect to written description. Biogen's counsel also noted that additional limitations in the dependent claims must be considered in assessing Defendant's prior art obviousness and anticipation defenses. (Tr. 911:1-17.) Counsel for Biogen then reiterated that Defendants bear the burden of proving invalidity as to all claim limitations. (Tr. 911:7-17.)

Regarding the Court's question "The claims, though, do say that in addition to it being the 480 milligram dose, that it has to be therapeutically effective. Right? Do you need to have a description in the patent of 480 being therapeutically effective?" (Tr. 926:24-927:3), Biogen's counsel responded as follows:

> It depends on what you meant by that question, Your Honor. We believe there is a description, it says a therapeutically effective amount to treat the MS characteristics and then defines what that amount is. We do not -- there is no requirement that you therefore go beyond that and then actually show that it was effective doing clinical trials showing testing that it actually worked in your patent.

(Tr. 927:4-11.) Counsel thus noted that the answer was dependent on what was meant by the question and then addressed the disclosures in the patent specification directed to therapeutic efficacy (a limitation in asserted independent Claims 1 and 15). (Tr. 927:4-11.)

To be clear, Biogen contends that the patent specification adequately describes the therapeutic efficacy limitation recited in asserted independent Claims 1 and 15. (D.I. 359 at PDF

pages 15-17 of 39, Biogen's Responsive Post-Trial Brief at pp. 7-9 (discussing support for the therapeutic efficacy limitation).) Claim 11 does not recite a therapeutic efficacy limitation, but even if such a limitation were to be read into the claim as Defendants argue, such a limitation is adequately described.

Second, Biogen's interrogatory response relating to the legal issues of obviousness and anticipation also does not support Defendants' argument. This interrogatory response does not include any statement that "all asserted claims of the '514 patent require a 'therapeutically effective' dose" as Defendants contend, and in the full context of the response it is apparent this was not the intent of the response. Rather, this response rebutted specific arguments that *Defendants* advanced in support of their anticipation defense based on the WO '342 patent application. In doing so, Biogen first disputed that the WO '342 reference "disclose[s] a daily dose of 480 mg/day to treat MS." (DEF Reply Ex. B at 15.) Then, as a further response, Biogen disputed that the WO '342 reference discloses other elements "include[d]" in the '514 patent claims. (*Id.*) Biogen never argued or suggested that all asserted claims contain a therapeutic efficacy limitation. There is likewise no such argument or statement in the pretrial submissions Defendants cite, DEF Reply at 1, which again relate to elements included in certain claims. The section of Biogen's Responsive Post-Trial Brief that responds to Defendants' argument that the prior art taught a "range of effective doses" (cited at DEF Reply at 2), similarly does not indicate Biogen agrees that all asserted claims contain a therapeutic efficacy limitation. (D.I. 359 at PDF page 35 of 39, Biogen's Responsive Post-Trial Brief at pp. 27-28.)

Finally, Defendants' assertion that judicial estoppel applies is misplaced. As the Third Circuit has explained, judicial estoppel is an "extraordinary remedy" and "[i]is not meant to be a technical defense for litigants seeking to derail potentially meritorious claims . . . ." *Ryan*

Operations G.P. v. Santiam-Midwest Lumber Co., 81 F.3d 355, 365 (3d Cir. 1996). Unlike a party against whom judicial estoppel might apply, Defendants have not shown and cannot show that Biogen took irreconcilably inconsistent positions concerning claim scope or "therapeutic efficacy" much less changed its position in bad faith, both of which are prerequisites for judicial estoppel. *Krystal Cadillac-Oldsmobile GMC Truck, Inc. v. GMC*, 337 F.3d 314, 319-320 (3d Cir. 2003).

III. CONCLUSION

Defendants' arguments are simply incorrect. Biogen did not concede that Claim 11 contains a therapeutic efficacy limitation. Thus, Defendants' arguments regarding alleged waiver and judicial estoppel are irrelevant.

ASHBY & GEDDES

/s/ Andrew C. Mayo

Steven J. Balick (#2114)
Andrew C. Mayo (#5207)
500 Delaware Avenue, 8th Floor
P.O. Box 1150
Wilmington, Delaware 19899
(302) 654-1888
sbalick@ashbygeddes.com
amayo@ashbygeddes.com

Attorneys for Plaintiffs

Of Counsel:

James B. Monroe
Eric J. Fues
Laura P. Masurovsky
Paul W. Browning
Li Feng
Andrew E. Renison
John E. Nappi
Jeanette M. Roorda
Aaron G. Clay
FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER, LLP
901 New York Ave., N.W.
Washington, D.C. 20001
(202) 408-4000

Megan L. Meyers
FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER, LLP
271 17th Street NW, Suite 1400
Atlanta, GA 30363
(404) 653-6565

Dated: March 16, 2020